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April 4, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, room 1061
Rockville, Maryland 20852

Re: Docket No. 02N-0276 (Registration)

Dear Sir or Madam:

Hansen-Mueller Company welcomes this opportunity to provide comments to the U.S. Food and Drug Administration ("FDA") regarding the proposed rule to implement the food facility registration provision of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the "Bioterrorism Act" or "Act"). A large importer of various grain products, Hansen-Mueller brings oats and other bulk grain agricultural products into the United States principally to meet demand that is not met by U.S. production. We are a privately owned, U.S. company operating in the grain merchandising, elevator and milling business for 24 years. The primary responsibility of Hansen-Mueller is to handle, process and transport grain and feed products from suppliers to consumers. As a holder of grains for non-propagative use, Hansen-Mueller's grain storage silos and elevators would be required to register with FDA under the proposal.

Hansen-Mueller understands that Congress has directed FDA to address the security of the American food supply against acts of intentional contamination and is, of course, a strong supporter of rational efforts to accomplish this goal. We appreciate the agency's efforts to arrive at fair and effective implementing regulations within the time constraints and nature of the statutory requirements established by Congress. It is also important that FDA consider carefully the most efficient and effective means for accomplishing the intended goals.

As it stands, the proposal is over-inclusive and would impose an undue burden on grain and shipping industries, with no added practical benefit in preventing and responding to acts of intentional contamination and other public health emergencies. Specifically, the proposal would require owners, operators, or agents in charge of grain storage silos and elevators that are already licensed/approved by the U.S. Department of

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Agriculture (USDA) to register again with FDA, requiring the submission of much duplicative information. In addition, the proposed rule would ostensibly require the registration of river barges that transport and hold grains--a difficult, if not impossible, proposition with which to comply as well as enforce. Finally, the proposal appears to exceed the scope of the Bioterrorism Act in that we do not view the registration requirement as applicable to facilities dealing solely in animal feed.

Hansen-Mueller, therefore, respectfully requests FDA to exempt from the registration requirement grain storage facilities licensed/approved by USDA, as well as facilities dealing solely in animal feed. Moreover, we encourage FDA to clarify in the final rule that carriers of bulk grains, such as river barges, are not required to register. Our concerns are outlined in further detail below and echo, in part, the comments Hansen-Mueller submitted to the Office of Management and Budget, attached for your reference.

I. FDA Should Exempt Grain Storage Facilities Licensed/Approved By USDA

Hansen-Mueller requests the agency to exempt from the registration requirement grain storage silos and elevators licensed by USDA's Farm Service Agency ("FSA") under the U.S. Warehouse Act and approved by USDA's Commodity Credit Corporation ("CCC") to store government and price-support grain. Combined, these voluntary programs require the submission of voluminous registration information, inspections of facilities for cleanliness and safety, and audits of the facility finances and inventory. The exacting regulatory framework applies to all firms that obtain voluntary USDA registration under the aforementioned programs. The exclusion of firms from the duplicative FDA requirements would only apply to firms that are already registered by USDA.

Licensed/approved facilities already submit to USDA much of the information that facilities would have to submit to FDA under the proposal. In addition to the facility name and address and manager/supervisor's name and contact information, information submitted to USDA includes the names and home addresses of the officers of the corporation, specific physical characteristics of the subject facility, articles of incorporation, and financial statements. To the extent that certain information required by the proposal is not provided to USDA, the facilities could submit supplemental information to the agency to ensure that it would have all information required under the Bioterrorism Act. In this fashion, FDA could capitalize and realize the efficiencies to be gained given the USDA registration requirements applicable to facilities participating in the existing USDA licensing and approval programs.

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USDA's first-hand knowledge of the licensed facility, along with the voluminous information provided to obtain the approval to store government and price-support grain, provides FDA an excellent opportunity for implementing the registration requirement in a fashion that does not needlessly create federal redundancies. Indeed, Hansen-Mueller believes USDA would be the most appropriate agency to respond to acts of intentional contamination or other public health emergencies, making registration with FDA unnecessary. This requested change to the proposal would preclude duplicative government regulation at the outset, rather than having to go back and "fix" the problem at some point in the future.

Hansen-Mueller believes that Congress granted FDA the discretion to exempt from the registration requirement those facilities licensed by USDA and approved to store government and price-support grain. Rep. Shimkus (R-Ill.), a member of the Conference Committee for the bill, stated explicitly that FDA should "exercise [its] discretion in the development and implementation of registration regulations to ensure that registration requirements are neither burdensome nor disruptive of the smooth flow of commerce." 1/ Exempting grain storage facilities licensed and approved by USDA would eliminate the registration burden on such facilities, while ensuring that a relevant federal agency has adequate information to assist it in accomplishing the main goal of the registration provision, namely identifying and locating quickly those grain storage facilities that are connected with a food product that poses a threat of serious adverse health consequences or death.

II. FDA Should Clarify That Grain Carriers Do Not Have To Register As Facilities Under The Act

Hansen-Mueller also requests FDA to clarify in the final rule that the Bioterrorism Act does not require the registration of grain carriers, such as river barges, that store food. In the Conference Report to the legislation, the Managers explicitly state that the registration requirement is not intended to apply to motor carriers that receive, carry, hold, or deliver food "in the usual course of business as carriers." 2/ It is our understanding, however, that FDA's proposal would require river barges that carry and hold grain "in the usual course of business," to register with FDA, which would impose an enormous burden on both the grain and shipping industries.

1/ 148 CONG. REC. H2858 (May 22, 2002)(statement of Rep. Shimkus).

2/ H.R. CONF. REP. NO. 107-481, at 134 (May 21, 2002).

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Specifically, the proposal would define "facility" to include "a mobile facility traveling to multiple locations that . . . holds food for consumption in the U.S." "Holding" would be defined as the "storage of food." River barges customarily pick up grain from one location and travel to an alternate location where the barge may store the product in its hull for several months prior to delivering the shipment to the ultimate consignee or purchaser. Thus, it appears that the proposal would require grain carriers to register with FDA as a "mobile facility" that "holds" food.

The impracticality of requiring registration of carriers is evidenced by the very nature of these vessels and the manner in which they are used. River barges and other carriers are constantly on the move, used interchangeably by numerous different companies, and do not have permanent addresses. Moreover, carriers do not always transport the same type of cargo. For example, the same vessel that carries bulk grains for one shipment, may carry completely different types of cargo, even non-food items, during subsequent voyages, requiring the constant submission of cancellations and amendments to registrations. It is these qualities of motor carriers, including river barges, that Congress presumably contemplated in determining to exempt carriers that hold food in their usual course of business from the registration requirement.

III. Application of the Bioterrorism Act's Registration Requirement to Animal Feed

Hansen-Mueller also requests FDA to exempt facilities dealing solely in animal feed from the registration provision. Based on the language of the provision and relevant legislative history, it appears that Congress intended to exempt such facilities from the requirement.

Throughout the legislative history of the Act, the registration provision is framed as applying to facilities that deal in food for human consumption. For instance, in discussing the final language of the Act, Rep. Shimkus (R-Ill.) stated repeatedly that the registration requirement is intended to apply to facilities that manufacture, process, pack, or hold "human" food for consumption in the U.S.

- "A new Section 415 of the FFDCA would . . . require that the Secretary implement an expansive program of registration of facilities engaged in the manufacture, processing, packing or holding of food for *human* consumption . . ."

- "The bill would authorize the Secretary to broadly impose the registration requirement to domestic facilities engaged in processing or distributing food for *human* consumption." 3/

In addition, as noted by FDA, the Conference Report on the legislation states that the retail exemption to the registration requirement applies to facilities that sell food directly to the retail consumer "for human consumption."4/ The complete absence of any reference to animal food in connection with the registration provision, along with the statements specifically tying the registration requirement to food for human consumption, indicates that Congress intended to exempt animal feed facilities from the registration requirement. 5/

We do note that other provisions of the Bioterrorism Act, including recordkeeping, administrative detention, and prior notice, reference certain requirements in terms of animal, as well as human food. Those sections are inherently broader than the registration provision, however. For instance, the Act's recordkeeping requirements apply to several types of food-related facilities that the Act specifically exempts from the registration provision, including facilities that transport food and, it appears, retail food stores. Thus, it would not be inconsistent for the Act to apply the recordkeeping and other provisions to animal feed facilities while at the same time exempting such facilities from the registration provisions.

* * * *

It is important that industry and government undertake all reasonable measures to enhance our homeland security. At the same time, in creating new regulatory requirements, it is imperative that FDA not lose sight of sound principles of good government, including avoidance of fashioning rules that are not meant to, nor should apply to all entities covered by overly broad definitions of the types of entities to be regulated.

3/ *Emphasis Supplied.* 148 CONG. REC. H2858 (May 22, 2002) (statements of Rep. Shimkus).

4/ H.R. CONF. REP. NO. 107-481, at 133 (May 21, 2002).

5/ The language of the Bioterrorism Act reinforces this conclusion. The registration provision provides that FDA may, if it determines it is necessary through guidance, require submission of "the general food category (as identified under section 170.3 of title 21, Code of Federal Regulations) of any food manufactured, processed, packed, or held at such facility." Section 170.3 categories apply solely to human food, however.

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Thank you for your consideration of our views. We welcome the opportunity to provide any additional information or assistance.

Sincerely,

John W. Orr
Hansen-Mueller Company, President

Enclosure